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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,121	01/17/2002	Cato T. Laurencin	DRE-0067	1682

7590 10/08/2004

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
	1651

DATE MAILED: 10/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/052,121	LAURENCIN ET AL.	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 July 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3,5 and 6 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date, _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/5/02</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

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DETAILED ACTION

In a response of 7/23/04 to a restriction requirement of 6/23/04, applicants elected Group I claims 1-3, 5 and 6 with traverse.

The traverse is on the ground that a search for invention I will

5 reveal art relating to invention II, and therefore a serious burden will not be placed on the examiner if the restriction is not made.

However, while one might accidentally find invention II in a search for invention I, due to the differences in inventions I and II as claimed, one would not necessarily have to find invention II when 0 searching for invention I, and invention I could be found without finding invention II. After finding invention I, the additional searching required to find the specific aspects of invention II not found in invention I will be a serious burden.

For the above reasons and for reasons in the restriction 5 requirement, the restriction requirement is still considered proper and is adhered to and made final.

Claim 4 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the 0 restriction (election) requirement in the reply filed on 7/23/04.

Claims examined on the merits are 1-3, 5 and 6.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5

Claims 1-3, 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10

The claims are confusing and unclear by claim 1 reciting "lighter than water or light as water microcarriers". Being "light" is relative and subjective, and can represent color. It is suggested that the microcarriers be required to have a density equal to or less than the density of water as set forth in the specification at page 7, lines 1-3.

15

Claim 1 is unclear as to the relationship of the microcarriers to the scaffold. Are the microcarriers the scaffold or is there some other relationship?

20

In line 2 of claims 3 and 6, "osteoblast-like" is uncertain as to meaning and scope. Being "like" is relative and subjective, and a cell that is like an osteoblast cell is a matter of individual interpretation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5 Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Devin et al (document AE on PTO-1449).

The claim is drawn to scaffold for tissue engineering comprising a biodegradable polymer-based lighter than water or light as water microcarriers.

10 Devin et al disclose degradable polymer-ceramic 3-dimensional composite matrices for use as a bone graft material. The matrices are porous and are an aggregate of polymeric microspheres (page 662, second paragraph under "Matrix fabrication" and page 663, under "RESULTS").

15 The matrices obtained by Devin et al are a scaffold as presently claimed, and the microspheres inherently have a density less than or equal to the density of water.

Claim Rejections - 35 USC § 103

20 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

25 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering 30 patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devin et al in view of Spaulding (6,001,643) and Granet et al (AJ on 1449), and if necessary in further view of Kusano et al (5,006,467), Henderson (4,448,884) or Starling et al (6,210,715 B1).

The claims require seeding the scaffold of claim 1 with cells and culturing *in vitro* in a rotating bioreactor.

Devin et al is described above.

Spaulding discloses culturing cells in a roller bottle for implanting to produce tissue. Microcarrier beads having densities less than the cell culture medium can be used for cell attachment to constrain tissue constructs to the area surrounding the annular axis and away from the cylinder wall of the bottle (col 16, lines 25-30).

Granet et al disclose culturing osteoblastic cells on microcarriers in a rotating-wall vessel (page 514, section 2.1.2).

It would have been obvious to use the matrices of Devin et al for cell culture in a roller bottle as disclosed by Spaulding or in a rotating-wall vessel as disclosed by Spaulding since these culturing techniques are intended for culturing cells on a carrier. It would

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have been further obvious to provide the matrices with a density less than or equal to that of water as suggested by Spaulding so the matrices will surround the axis away from the wall. If needed Kusano et al (col 2, line 66), Henderson (col 2, line 12) or Starling et al (col 6, lines 59-61 and col 10, line 38) would have further suggested a density equal to that of water from disclosing cell culture with a microcarrier having a density of 1 g/ml or 1 g/cc. Culturing of osteoblast cells would have been obvious and if needed suggested by Granet et al since these cells produce bone as desired by Devin et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for 5 unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

DMN
10/6/04